

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	<u>7-29-99</u>
Publication Date	<u>7-30-99</u>
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Food and Drug Administration

[Docket No. 97P-0350]

Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment the recommendation of the Obstetrics and Gynecology Devices Panel (the Panel) to reclassify the home uterine activity monitor (HUAM) from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by Corometrics Medical Systems, Inc., and other publicly available information. FDA also is announcing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that provides 510(k) applicants with specific directions regarding data and information that should be submitted to FDA in 510(k) submissions for HUAM's.

DATES: Written comments by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new

devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

A. Preamendments Devices

Before enactment of the 1976 amendments, tokodynamometers, integrated into electronic perinatal monitoring systems, were in commercial distribution. A tokodynamometer is a transducer and monitoring system used to make continuous external (abdominal) measurements of intrauterine pressure and provide strip chart tracings of the uterine contractions of a pregnant woman during labor. Preamendments perinatal monitors were marketed as systems for use in clinical settings, with different models for the office or hospital, and intended for clinical evaluation of the fetus and mother. In 1980, FDA classified these preamendments monitors (external uterine contraction monitor (21 CFR 884.2720) and perinatal monitoring system (21 CFR 884.2740) into class II.

B. Premarket Notifications

Between 1984 and 1987, FDA reviewed 510(k)'s for several HUAM's and found these HUAM's to be substantially equivalent to tokodynamometers used in clinical settings. HUAM manufacturers were permitted to market these devices for use in "low risk at-term" pregnancies. However, FDA determined that use of the HUAM for "the early detection of preterm labor (PTL) in high risk patients" constituted a new intended use. For this new use, FDA determined that the HUAM was not substantially equivalent to any preamendments class I, class II, or class III device not subject to an approved PMA, or to any postamendments device that had been classified into class I or class II for the early detection of PTL. Accordingly, FDA advised HUAM manufacturers that the device was classified into class III under section 513(f)(1) of the act, and that it could not be placed in commercial distribution for early detection of PTL in high risk patients unless it was reclassified under section 513(f)(2), or subject to an approved PMA under section 515 of the act.

C. PMA Reviews and Related Issues

Subsequent to 1987, several PMA's for HUAM's were submitted to FDA and referred to the Panel for its recommendations.

On May 26, 1988, the first PMA the Panel considered was the Tokos' Term Guard™ device. The Panel recommended that this PMA not be approved because the supporting data did not show the individual contribution the monitor made to the early detection of PTL, over and above that attributable to the regimen of daily patient contact (Ref. 1).

On March 6, 1989, the Panel reviewed a PMA submitted by Healthdyne, Inc., for its System 37™ HUAM and recommended that the PMA be found not approvable because the primary study endpoint (physician intervention) was considered too subjective and the study lacked a control group (Ref. 2).

On January 18 and April 4, 1990, the Panel reviewed a PMA submitted by Physiological Diagnostic Systems, Inc., for its Genesis™ HUAM. This PMA was supported by a randomized controlled clinical study that demonstrated the individual contribution of the monitor to the early detection of PTL, as evidenced by cervical dilation at the time of PTL diagnosis. These data, within the study, were compared with the standard care for high risk patients without monitoring. On the basis of this data, the Panel recommended approval of the Genesis™ HUAM for the early detection of PTL in only one high risk patient group (Refs. 3 and 4). Subsequently, on September 12, 1990, FDA approved a PMA for the Genesis™ HUAM. This HUAM is indicated for use, in conjunction with standard high risk care, for the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with a history of previous preterm birth. With the Genesis™ system, uterine activity is displayed at a remote location to aid in the early detection of PTL, as evidenced by cervical dilation at the time of PTL diagnosis (Ref. 5).

On June 11, 1990, the Panel reviewed a new PMA from Healthdyne for its System 37™ HUAM. Healthdyne submitted new data and claimed that the System 37™ would identify women, already known to be a high risk for PTL, who were at an even higher risk of preterm birth. The

Panel recommended that this PMA not be approved because of inherent study design flaws. In particular, the outcome variable (incidence of preterm birth) had significant intra and interobserver variation, and the study entry criteria were biased (Ref. 6).

On April 29 and 30, 1993, the Panel reviewed a PMA for the DT 100-P HUAM manufactured by Advanced Medical Systems. This HUAM system was indicated for the early detection of PTL in women with twin gestations. The Panel reviewed the PMA and recommended that the PMA be found not approvable because all the key clinical data came from only one site and because significant engineering questions regarding the monitoring system were unanswered.

The Panel also considered several FDA prepared questions on the interpretation of clinical study findings supporting other PMA's under review. In addition, the Panel addressed certain issues relative to the existing draft guidance document entitled "Premarket Testing Guidelines for Home Uterine Activity Monitors" (March 31, 1993). Issues discussed included: (1) The use of a random sample of examiners to address intra and interobserver variance; (2) the use of a standard definition for the terms "preterm labor" and "standard of care for high risk patients"; (3) limiting study inclusions to a minimum gestational age of 20 weeks; and (4) allowing the use of subgroup analysis, except for the purpose of making promotional claims. The Panel also noted the importance of blinding procedures for patients and investigators, but did not go so far as to identify it as a requirement.

During the April 1993 meeting, the Panel stressed that FDA should look at how the HUAM device is promoted and how often it is used for indications for which it is not approved in the context of postapproval studies or annual reporting (Ref. 7). Also, during this meeting, FDA informed the industry that in light of the many published studies on HUAM's, the devices were a good candidate for reclassification and invited them to petition FDA for a change in classification of the devices.

During the Panel meeting of September 2, 1994, FDA sought additional guidance regarding clinical review issues on HUAM PMA's. The Panel reconsidered whether cervical dilation at the

time of PTL diagnosis should remain the primary clinical endpoint. Alternative endpoints were discussed and despite the difficulties and imperfections of using cervical dilation, the Panel concluded that this endpoint should remain an acceptable alternative for HUAM efficacy studies (Ref. 8).

During the Panel meeting of April 24, 1995 (Ref. 9), Caremark, Inc., presented the clinical efficacy study results for its First Activity® HUAM. The study included design elements specifically recommended and preferred by the Panel, including a sham control. When compared to standard clinical care for high risk patients, the study showed no added benefit when using an HUAM for either early PTL detection or reduced preterm births. These findings did not persuade the Panel to change its earlier recommendations regarding acceptable elements of study designs.

On September 29, 1995, FDA approved PMA's for Healthdyne's System 37™ and CareLink Corp.'s CareFone™ HUAM's, for the same indication as the Genesis™ HUAM; i.e., in conjunction with standard high risk care, the HUAM was approved for the daily at-home measurement of uterine activity in pregnancies, ≥ 24 weeks gestation, for women with a history of previous preterm birth. The uterine activity of these devices is also displayed at a remote location to aid in the early detection of PTL.

D. Reclassification Petition

On August 15, 1997, FDA received a petition from Corometrics Medical Systems, Inc., for its Model 770 BMS HUAM system requesting FDA to reclassify the HUAM system from class III to class II under section 513(f)(2) of the act and § 860.134, based on information submitted in the petition (Ref. 10).

Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested change in classification.

III. Device Description

A home uterine activity monitor is an at-home monitoring system that consists of a tocotransducer and abdominal belt, an at-home recorder/memory system, a telephone data transmitter (at-home modem), and a separate data receiving, storage, and display system that is located, remote from the home, in a clinical setting (data receiving center). The device is intended to be used on women with a previous preterm delivery to aid in the detection of PTL.

At home, per instructions by the obstetrician, a pregnant woman secures the tocotransducer around her abdomen for a specified duration and frequency. Uterine muscular distention (tone) changes, indirectly detected by the tocotransducer, are recorded and stored in the recorder/memory. Either immediately after recording or at a later time, the uterine activity data is transmitted via the modem to the data receiving center for clinical evaluation.

The receiving center has a computerized system with specialized software to receive, store, and display the uterine activity data for clinical evaluation at the remote clinical site. Based on the evaluation of the uterine activity tracing, the patient is referred to her obstetrician for further followup to determine whether she has started PTL.

IV. Recommendations of the Panel

In a public meeting on October 7, 1997, the Panel unanimously recommended that the HUAM be reclassified from class III to class II for use in early detection of PTL, as evidenced by cervical dilation at PTL diagnosis, for women with a previous history of preterm birth (Refs. 11 and 12). The Panel believed that class II with special controls of patient registries, bench testing, consensus standards, and clinical validation studies would provide reasonable assurance of the safety and effectiveness the device.

V. Risks to Health

During its review and discussion of the proposed reclassification of the HUAM, the Panel identified certain risks to health they believed were associated with use of the HUAM. The risks

were identified as : (1) Off-label use; (2) initiation of a cascade of interventions including bed rest, hospitalization, and medications; and (3) disabilities and psychological concerns, such as quality of life issues. The Panel had other concerns they believed were hazards to health. They identified the specific hazards as needless exposure to tocolytics and steroids resulting from detection of clinically meaningless contractions, alterations in quality of life from false positives, and inability to identify contractions because of a failure of the transducer to be sensitive and specific.

After considering the discussion by the Panel during the reclassification proceedings, reviewing the reclassification petition, medical device reports, and published literature, FDA identified the following risks it believed are associated with use of the HUAM when used in early detection of PTL, as evidenced by cervical dilation at PTL diagnosis, for women with a history of previous preterm birth:

A. Electric Shock and/or Injury

HUAM's are electrically powered devices which can cause electrical shock to the patient or clinician, leading to injury or death. This potential risk is well understood, and it can be mitigated by appropriate system design such as sufficient electrical isolation and other safety measures in accordance with applicable consensus standards.

B. Skin Irritation and Sensitization

HUAM's have accessories that make contact with the skin, namely, the tocotransducer and abdominal belt. Any material that comes in contact with the skin has the potential for causing skin irritation and sensitization. This risk can be lessened, if it occurs, by a consensus standard for material safety.

C. Unnecessary Evaluation and Treatment

Unnecessary evaluation and treatment may result from an imprecise definition of PTL or failure of an HUAM to accurately depict uterine activity. Diagnosis of PTL is often difficult, and

many times can only be confirmed retrospectively by the preterm delivery. Nonetheless, the consequences of preterm delivery can be devastating in terms of neonatal morbidity and mortality. There is a concern that the use of an HUAM system can cause unnecessary visits to the clinic which could, in turn, lead to over-diagnosis of PTL and unnecessary treatment with tocolytics for women who have increased uterine activity but are not destined for preterm delivery. Improper device design or a malfunctioning device can also result in an apparent increase in uterine activity and unnecessary clinical visits, thereby leading to unnecessary treatment with tocolytic agents intended to stop or slow labor.

D. Disabilities and Psychological Issues

Physical disabilities and psychological burdens may result from the clinical management of women diagnosed with PTL. For example, the use of some tocolytic agents sometimes causes temporary or permanent injury to the mother. Moreover, the HUAM regimen coupled with a tocolysis regimen can significantly disrupt a woman's pregnancy and her quality of life. Nonetheless, it is noted that a high risk pregnancy is often psychologically debilitating to the patient, and tocolytics may be prescribed for unmonitored women as well.

E. Other Risks From Use in Unproven Patient Populations

HUAM's have only been approved for use on women who have had a previous preterm delivery. The overuse of HUAM's for other indications, i.e., PTL in the current pregnancy, multiple gestations, etc., were expressed concerns of the Panel. The clinical utility for these other indications has not been proven.

VI. Benefits

HUAM's provide a benefit to high risk patients by helping to detect PTL at an early stage, as evidenced by cervical dilation, thereby allowing for early management of PTL. Early detection of PTL increases the likelihood of successful tocolysis, leading hopefully to the ultimate benefit of fewer preterm births and lower infant mortality and premature births. However, because this

is only a monitoring device, FDA has required HUAM manufacturers to show that the devices provide contraction information that contributes to the diagnosis of PTL. Manufacturers are not required to show a reduction in the outcome measures because they are a result of successful intervention after diagnosis.

HUAM technology is well-established with a long history of safe use at home and in the clinical setting. HUAM device design does not vary substantially from manufacturer to manufacturer in terms of underlying technology and clinical performance. Specific design choices are not expected to affect the risk to the patient. Therefore, FDA believes that randomized controlled clinical studies intended to show early PTL detection are no longer necessary and that the special controls described in section IX of this document would provide reasonable assurance of the safety and effectiveness of the device.

VII. Summary of Reasons for Recommendation

After reviewing the data and information contained in the petition and provided by FDA, and after consideration of the open discussions during the Panel meetings and the Panel members' personal knowledge of and clinical experience with the device, the Panel gave the following reasons in support of its recommendation to reclassify the generic type HUAM for use, in conjunction with standard high risk care, in the daily at-home measurement of uterine activity in pregnancies ≥ 24 weeks gestation for women with a history of previous preterm birth from class III into class II:

1. The Panel believes that general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness.
2. The Panel believes that the HUAM should be reclassified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

VIII. Summary of Data Upon Which the Panel Recommendation is Based

The Panel considered a large number of published clinical studies ranging in size, control, study population, and outcome measures (Ref. 10). Statistical analyses of various studies were also considered. The Panel believed that these studies, as an aggregate, established the effectiveness of HUAM's, and qualified their effectiveness as an adjunctive tool for monitoring high risk pregnancies. At least one study showed that when HUAM's are used in combination with daily nursing care, PTL can be detected earlier than it is detected by the standard clinical management of patients at high risk for PTL (Ref. 12). Other studies showed that when used without daily nursing contact, HUAM's detected PTL earlier (as evidenced by cervical dilation at the time of PTL diagnosis) than standard clinical care of a select patient populations (Refs. 5 and 14). On the other hand, some controlled studies showed that, for high risk populations, HUAM's do not contribute to PTL detection rate or a reduction in preterm deliveries when used with daily nursing contact (Refs. 15 and 16). Some studies evaluated HUAM's for managing pregnant women who were at risk for preterm birth for other reasons, e.g., multiple gestation and PTL in the current pregnancy (Refs. 5, 12, 13, 14, 15, and 16). The Panel did not evaluate the evidence for these indications.

Most of the risks associated with HUAM's identified by the Panel were indirect effects attributable to incorrect monitoring information or misinterpretation of monitoring information leading to misdiagnosis. The concern that the use of the device would result in an increase in the number of hospital visits and use of tocolytics was not borne out in the published literature. The potential risk of misdiagnosis is one that is generally mitigated by proper training, adequate labeling, and limited use of the device by the clinician.

Based on the available information, FDA believes that the special controls discussed in section IX of this document are capable of providing reasonable assurance of the safety and effectiveness of the HUAM with regard to the identified risks to health of this device.

IX. Special Controls

In addition to general controls, FDA believes that the special controls (patient registries and guidance document) discussed in this section are adequate to control the risks to health described for this device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document entitled “Home Uterine Activity Monitors: Guidance for the Submission of 510k Premarket Notifications” that provides 510(k) applicants with specific directions regarding data and information that should be submitted to FDA in 510(k) submissions for HUAM’s.

A. Patient Registries

The rationale for using patient registries is that it provides a means for characterizing the nature of the patient population for which the device is actually used and to track information about the labor and delivery of women for whom the device was prescribed. FDA believes that using patient registries, in a structured sampling format, will provide outcome data that will contribute to appropriate use of the device.

B. Guidance Document (Home Uterine Activity Monitors: Guidance for the Submission of Premarket Notifications)

This document incorporates: (1) The consensus standards from professional organizations to provide uniformity, (2) bench testing and validation study information to validate the effectiveness and performance of the device, and (3) labeling to describe the device’s capabilities and discourage off-label use.

1. Bench Testing

Bench testing can validate the ability of the HUAM to operate (independently or in combination with clinical validation studies) as intended, i.e., to collect, store, and transmit data. Bench testing can also address the risk of false positives and the resulting inappropriate management of the patient. Appropriately designed bench testing will ensure that uterine activity,

and contractions in particular, are accurately measured and displayed by the device, thereby minimizing false positives associated with the device.

2. Consensus Standards

The International Electrotechnical Commission (IEC) standards 601–1 for medical electrical equipment and 601–1–2 for general safety identify the electrical safety and electromagnetic compatibility aspects for any type electrical device. Adherence to these standards can control the risks of electrical shock and/or injury to the patient and clinician. Copies of these standards may be obtained from IEC, AT3, Rue de Varembe, P.O. Box 131, Geneva, Switzerland, CH–1211. IEC also maintains a site on the world wide web at “<http://www.iec.ch>”. Testing in accordance with any of a variety of material safety consensus standards, such as ISO–10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, can minimize the risks of skin irritation and sensitization caused by the tocotransducer and abdominal belt. Copies of this and other material safety standards may be obtained from International Organization for Standardization, Case Postal, Geneva, Switzerland, CH–1121. ISO also maintains a site on the World Wide Web at “<http://www.iso.org>”.

3. Clinical Validation Study

The rationale for using a clinical validation study is to address the risk of false positives and the resulting inappropriate management of the patient. The objective of this limited clinical validation study is to address the remaining performance issues of the device, namely, the recording and data transmission functions that cannot be addressed via bench testing. The system should be tested in a small clinical study, in its intended setting with actual subjects. The study endpoints should address the readability of the received tracings, i.e., are the contractions correctly perceived by the clinician. The outcome of a limited clinical validation study would address and possibly mitigate the risk of unnecessary evaluation and treatment of the patient.

4. Labeling Requirements

Labeling addresses the risk of use of the device in unproved patient populations. Diagnosis of PTL is often difficult, and many times can only be confirmed retrospectively by the actual preterm delivery. Yet, the consequences of preterm delivery can be devastating in terms of neonatal morbidity and mortality. An HUAM system that causes additional visits to a clinic could lead to over-diagnosis of PTL and unnecessary treatment with tocolytics for women who have increased uterine activity but are not destined for preterm delivery. Labeling should provide an accurate description of the device's capabilities and discourage the off-label use of the device and limit the perpetuation of false claims of the device's capabilities.

FDA believes labeling which describes the capabilities and limitations of the HUAM system device can lead to a more informed use of this technology by the clinician, thereby mitigating the risks of unnecessary evaluations and treatments, disabilities, and psychological issues.

X. FDA's Tentative Findings

The Panel and FDA believe that the HUAM should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to established special controls to provide such assurance.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, May 26, 1988.
2. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, March 6, 1989.
3. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, January 18, 1990.
4. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, April 4, 1990.

5. Mou, S. M. et al., "Multicenter Randomized Clinical Trial of Home Uterine Activity Monitoring for Detection of Preterm Labor," *American Journal of Obstetrics and Gynecology*, 165(4):858–866, 1991.
6. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, June 11, 1990.
7. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, April 29 and 30, 1993.
8. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, September 2, 1994.
9. Obstetrics and Gynecology Devices Panel Meeting, Summary Minutes, April 24, 1995.
10. Reclassification Petition Submitted by Corometrics Medical Systems, Inc., June 5, 1997.
11. Obstetrics and Gynecology Devices Panel Meeting, Transcript, October 7, 1997.
12. Hill, W. C. et al., "Home Uterine Activity Monitoring is Associated With a Reduction in Preterm Birth," *Obstetrics and Gynecology*, 76 (1 Supplement):13s–18s, 1990.
13. Dyson, D. C. et al., "Prevention of Preterm Birth in High Risk Patients: The Role of Education and Provider Contact versus Home Monitoring," *American Journal of Obstetrics and Gynecology*, 164(3):756–762, 1991.
14. Wapner, R. J. et al., "A Randomized Multicenter Trial Assessing a Home Uterine Activity Monitoring Device Used in the Absence of Daily Nursing Contact," *American Journal of Obstetrics and Gynecology*, 172(3):1026–1034, 1995.
15. Blondel, B. et al., "Home Uterine Activity Monitoring in France: A Randomized, Controlled Trial," *American Journal of Obstetrics and Gynecology*, 167(2):424–429, 1992.
16. Iams, J. D., F. F. Johnson, and R. W. O-Shaughnessy, "A Prospective Random Trial of Home Uterine Activity Monitoring in Pregnancies at Increased Risk of Preterm Labor, Part II," *American Journal of Obstetrics and Gynecology*, 150(3):595–603, 1988.

XII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XIII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

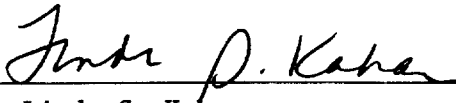
The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIV. Request for Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals

may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

Dated: 6/30/99
June 30, 1999



Linda S. Kahan
Deputy Director for Regulation Policy
Center for Devices and Radiological Health

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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